

## **REMARKS**

Entry of the above amendments and reconsideration of the application are respectfully requested. Upon entry of the amendments, this application will contain claims 14-15, 18-30, 36-38 and 46-61 pending and under consideration. Applicants acknowledge with appreciation the indication of allowability of claims 14, 15, 26-29, 36-38, 46-48, 54-56, 60 and 61, and that claims 21 and 25 would be allowable if amended as suggested by the examiner. Independent claim 20 now includes the subject matter of previous claim 21. In light of the amendments made above and the comments which follow, it is believed that all other issues are removed and that this application is in condition for passage to allowance.

All present claim amendments find sufficient support in the original disclosure. Using sheets of compliant collagenous biomaterials to form tubes is discussed and shown throughout the specification, for example, as shown in Figures 5-7 and 10 and discussed in the related text. As well, having apertures extend through the sheet is also shown and discussed throughout the original disclosure, for example, as shown in Figures 5-7 and 10 and discussed in the related text. Having extensions of the sheet is also shown and discussed throughout the original disclosure, for example, as shown in Figures 4 and 14 and discussed in the related text. Additional support is found throughout the specification and original claims. No new matter is introduced by the present claim amendments.

### ***Claim Rejections – 35 U.S.C. § 112***

Claims 25, 30, 53 and 57-59 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Withdrawal of these rejections is requested in light of the above amendments, which are summarized as follows:

Claim 25 has been amended to recite "...each one of said plurality of extensions...."

Claim 30 has been amended to cancel the offending occurrence of "and";

Claim 53 has been amended to be dependent on claim 52.

### ***Claim Rejections – 35 U.S.C. § 102***

**Myers et al. (U.S. Patent No. 5,910,168)**

Claims 18-20, 22-24 and 30 stand rejected under 35 U.S.C. 102(e) as being unpatentable over Myers et al. (U.S. Patent No. 5,910,168).

**Claims 18-20 and 22-24**

As amended, independent claims 18, 20 and 23 each include features not taught by Myers, and therefore Myers cannot be considered a proper § 102 reference. For one, Myers does not in any way teach a compliant, sealed tube being formed with a sheet of biomaterial as claimed. In addition, Myers fails to teach the sheet defining a plurality of extensions, and a plurality of apertures providing openings extending through the sheet material. These features are simply not taught by Myers under any reasonable interpretation. For at least these reasons, none of claims 18-20 and 22-24 are anticipated by Myers, and thus withdrawal of these rejections is requested.

**Claim 30**

Claim 30 requires that the tube is “formed with a sheet of collagenous material” and further wherein the sheet defines a “plurality of extensions” and a “plurality of apertures extending through the sheet”. Claim 30 further requires that “each one of said plurality of extensions includes an extension portion received through a corresponding one of said plurality of apertures so as to overlie an underlying layer of material, wherein a surface of said extension portion conforms and is bonded to the underlying layer of material by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent.” Myers does not teach these features. For at least these reasons, claim 30 is not anticipated by Myers. Withdrawal of this rejection is therefore requested.

***Claim Rejections – 35 U.S.C. § 103***

**Myers et al. (U.S. Patent No. 5,910,168)**

Claims 49-53 and 57-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (U.S. Patent No. 5,910,168). In support of this rejection, the Office Action asserts

that Myers teaches all of the subject matter of each of these claims except for the use of submucosa. To the extent that this position is maintained, Applicants respectfully disagree.

To consider the obviousness question with regard to these claims, one must first look to the claims from which they depend. As discussed above, Myers fails to teach the elements of the base claims (i.e., claims 18, 20 and 30). In fact, Myers fails to teach or suggest anything close to the claimed medical devices including tubes formed with sheets having extensions and corresponding apertures, with the extensions extending of the sheet through the corresponding apertures of the sheet. As such, the base claims are not obvious over Myers, and neither are dependent claims 49-53 and 57-59. Withdrawal of this rejection is requested.

**Campbell et al. (U.S. Patent No. 6,027,779)**

Claims 18-20, 22 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (U.S. Patent No. 6,027,779).

As amended, independent claims 18, 20 and 30 each include features that are not taught or suggested by Myers. For one, all of these claims require a tube formed from a sheet of material, wherein the sheet includes apertures that extend through the sheet. Campbell does not in any way teach or suggest this feature. At most, Campbell teaches a pocket formed alongside a wall of a tube (e.g., a pocket between first sheet 21 and second sheet 22 as suggested by the Examiner in the Office Action). This is not an aperture extending through the sheet as claimed. Moreover, Campbell fails to teach anything remotely close to a plurality of extensions extending through a plurality of such claimed apertures. For at least these reasons, claims 18-20, 22 and 30 are patentably distinct from Myers, and withdrawal of this rejection is solicited.

**Wallace et al. (U.S. Patent No. 6,669,719)**

Claims 18-20, 22, 30, 49-53 and 57-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (U.S. Patent No. 6,669,719).

As amended, independent claims 18, 20 and 30 each include several features that are not taught or suggested by Wallace. All of these claims require a tube formed from a sheet of material, wherein the sheet defines a plurality of extensions and a plurality of apertures through the sheet, with the extensions received through the apertures. Wallace does not in any way teach

or suggest these features. For at least these reasons, claims 18-20, 22, 30, 49-53 and 57-59 are patentably distinct from Wallace, and withdrawal of this rejection is solicited.

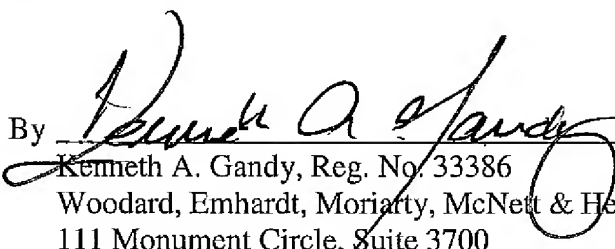
### **Conclusion**

In view of the above amendments and remarks, it is respectfully submitted that all rejections have been overcome and that the present application is in condition for allowance. Action to that end is solicited.

### **Request for Interview**

In the event that the Examiner finds any reason that the application cannot be allowed in its present form, the Applicants wish to conduct an interview with the Examiner prior to any next Office Action in order to provide an opportunity for coming to agreement upon allowable claims. To arrange the interview, the Examiner should call the undersigned attorney at the telephone number given.

Respectfully submitted,

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